GETEIN BIOTECHNOLOGY

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One Step Test for NGAL (Colloidal Gold)
For *In Vitro* Diagnostic Use

Manual

INTENDED USE

One Step Test for NGAL (Colloidal Gold) applies colloidal gold immunochromatography to detect neutrophils gelatinase associated lipocalin (NGAL) in urine samples quantitatively. This test is used as an aid in the early diagnosis of acute kidney injury, risk classification and treatment monitoring.

SUMMARY

The inclining incidence of chronic kidney disease which has led to high mortality and immense medical burden over the past decades has become a distressing concern in epidemiology. Unfortunately, the number of biomarkers that allow the monitoring of chronic kidney disease (CKD) is limited. NGAL is an emerging biomarker which has been shown to be able to diagnose kidney injuries.

The evidence for the role of NGAL measurements in a variety of clinical situations leading to AKI (cardiac surgery, kidney transplantation, contrast nephropathy, haemolytic uraemic syndrome and in the intensive care setting) or to CKD (lupus nephritis, glomerulonephritides, obstruction, dysplasia, polycystic kidney disease, IgA nephropathy) is explored. The emerging utility of standardized clinical platforms for reliable measurement of NGAL in plasma (Triage NGAL Device; Biosite Incorporated) and urine (ARCHITECT analyzer; Abbott Diagnostics) is also discussed. It will be important in future studies to validate the sensitivity and specificity of NGAL concentration measurements in clinical samples from large cohorts and from multiple clinical situations. Such studies will be facilitated by the anticipated widespread availability of standardized commercial tools in the near future.

PRINCIPLE OF THE EXAMINATION METHOD

The test uses an anti-human NGAL polyclonal antibody conjugated with colloidal gold and an anti-human NGAL monoclonal antibody coated on the test line. After the urine sample has been applied to the test strip, the gold-labelled anti-human NGAL polyclonal antibody binds to the NGAL in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human NGAL monoclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amout of NGAL in sample.

Then insert test card into the FIA8000 Quantitative Immunoassay Analyzer (hereafter referred to as FIA8000), the concentration of NGAL in sample will be measured and displayed on the screen. The values will be stored in FIA8000 and available for downloading on demand. The result can be transmitted to the laboratory or hospital information system, if it is connected to FIA8000.

CONTENTS

A kit contains:

1. Foil bag, which contains one test card and one desiccant ……25
2. Pipette……25
3. Manual ……1
4. SD card …… 1

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (a colloidal gold-labelled anti-human NGAL polyclonal antibody is coated at the border of the nitrocellulose membrane and sample pad, the test line is coated with an anti-human NGAL monoclonal antibody, and the control line is coated with rabbit anti-goat IgG antibody), absorbent paper and liner.

Note: Components from different batches cannot be exchanged.

MATCHING EQUIPMENT

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.
Use the test card within 1 hour once the foil bag is opened.

WARNINGS AND PRECAUTIONS

1. For *In-Vitro* diagnostic use.
2. For use by healthcare professionals.
3. Do not use the kit beyond the expiration date printed on the outside of the box.
4. Keep the test card in the sealed pouch until ready to use. Do not reuse the used cards.
5. The pipette should not be used for multiple samples. Discard it after single use.
6. Patient samples, used test cards and pipettes may be potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully follow the instructions and procedures described in this manual.

SAMPLE COLLECTION AND PREPARATION

1. A urine sample is required for testing with this product.
2. Urine sample can be preserved at room temperature only for 4 h, please test it as soon as possible. If testing cannot be completed immediately, the urine sample should be stored up to 3 days at 2~8°C until it can be tested.
3. Do not freeze urine sample. Urine sample in freezing preservation cannot be used for testing.
4. Samples must be recovered to room temperature before testing.
5. Avoid heating the samples, which can cause protein denaturation.
6. SAMPLE VOLUME: 120 µl urine.

TEST PROCEDURE

1. Restore samples and sealed test-card foil bags to room temperature before using. Open the foil bag, label cards with numbers and use the test cards immediately.
2. Confirm SD card lot No. in accord with test kit lot No.. Perform “QC SD” operation (Details refer to 8.3.1 of FIA8000 User’s Manual) when necessary.
3. Take 120 µl urine sample, drop vertically to the sample port on the test card.
4. Wait for 3 minutes, insert the card immediately into FIA8000 and press "OK" button, the test card can be detected and the result will be printed automatically.

Note:

1. It is required to perform “QC SD” operation when using a new batch of kits; Only one “QC SD” operation is required for the same batch.
2. Assure of card side towards FIA8000 is correct and insert the card completely.

TEST RESULTS

When a purplish-red band appears in the control area, use the FIA8000 to analyse the test card and get a quantitative result.

If no purplish-red band appears in the control area, it indicates that the operation is incorrect or the test card has passed its expiration date. In this case, please read the manual again carefully and use a new test card to try again, if the problem persists, please stop using all products of the same batch immediately and contact with your supplier.

EXPECTED VALUE

NGAL concentration is determined using samples obtained from 319 apparently healthy individuals. The 95th percentile of the concentration for

NGAL is 135ng/ml.

PERFORMANCE CHARACTERISTICS

Measurement Range: 50ng/ml~1500ng/ml
Minimum Detection Limit: ≤50ng/ml
Within-Run Precision: ≤10%
Between-Run Precision: ≤15%
Method Comparison:
Compared to Abbott I2000 analyzer and matching NGAL test kits with 200 patient urine samples (157 positive samples, 43negative samples). The correlation coefficient (r) is 0.989.

LIMITATIONS OF THE PROCEDURE

1. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.
2. Some substances in urine sample as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of them is as follows:

Interfering Substance	Concentration (Max)
Creatinine	10g/L
Glucose	10g/L
Urea	100g/L

REFERENCES

1. Wasilewska A, Taranta-Janusz K, Dębek W, et al. KIM-1 and NGAL: new markers of obstructive nephropathy. Pediatr Nephrol. 2011, 26(4): 579-586.
2. Clerico A, Galli C, Fortunato A, et al. Neutrophil gelatinase-associated lipocalin (NGAL) as biomarker of acute kidney injury: a review of the laboratory characteristics and clinical evidences. Clin Chem Lab Med. 2012, 50(9): 1505-1517.
3. Shemin D, Dworkin LD. Neutrophil gelatinase-associated lipocalin (NGAL) as a biomarker for early acute kidney injury. Crit Care Clin. 2011, 27(2): 379-389.
4. EN ISO 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for NGAL (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN 980: 2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration Date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE marking		

Thank you for purchasing One Step Test for NGAL (Colloidal Gold), Please read this manual carefully before operating to ensure proper use.

Version: 140318

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